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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,642	07/16/2007	Renato Monteiro	70078.0020USWO	2086

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
02/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,642	MONTEIRO ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-25* is/are pending in the application.

4a) Of the above claim(s) *7 and 20-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6 and 8-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/5/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response received December 2, 2009 is acknowledged.

Claims 1-4 have been canceled.

Claims 5-25 are pending in the instant application.

Applicant's election with traverse of group I, claims 5-19, as they read on methods of treatment, as well as the ultimate disease species of allergic asthma in the reply filed on December 2, 2009 is acknowledged. The traversal is on the ground(s) that claim 6 discloses subject matter not taught by WO 02/064634 and that therefore this is the technical feature shared amongst the inventions which entitles applicant to a finding of unity of invention. This is not found persuasive because claim 6 is a dependent claim. As such, its limitations are not shared by all of the claimed inventions. Since the features of claim 6 are not present in all claims, said features logically cannot be a special technical feature linking all the claimed inventions. Thus, the features shared among all the claims are present in the prior art and thus the finding of a lack of unity of invention is maintained. Further, the instant specification states that antibodies which bind the EC2 domain do not inhibit binding of IgA to FcαI. Antibodies which bind FcαI at a site different from the IgA binding site are disclosed by the '634 document, such as in lines 29-32 of page 2, as are Fab fragments which are monovalent (see lines 106 of page 3).

The requirement is still deemed proper and is therefore made FINAL.

Claims 7 and 20-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 2, 2009.

Claims 5, 6, and 8-19 are under examination as they read on administering antibodies which bind FcαRI to treat allergic asthma.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim recites the IgG1k antibody A77. Thus, A77 is a required element needed to practice the instant claimed method. As a required element, the A77 antibody must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent material. See 37 CFR 1.801-1.809.

The specification does not indicate that A77 has been deposited or that it is commercially available and thus is readily known and available to the public. Applicant is reminded that if A77 has been deposited in accordance with the Budapest Treaty, assurances that the recited material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, and assurances that said material will be replaced if the material becomes unviable still must be made.

If the deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that A77 has been deposited under the Budapest Treaty and that A77 will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample or for the enforceable life of the patent, whichever is longer. See 37 CFR 1.806 and MPEP 2410-2410.01. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the vector described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

4. Claim 12 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting bronchial hyperreactivity, does not reasonably provide enablement for prevention of said reactivity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant has claimed a method of preventing bronchial hyperreactivity by administering antibodies which bind FcαRI/CD89. The specification does not appear to define the term “preventing” but it is reasonable that this term encompasses stopping a reaction from ever occurring, something which is not often logically possible since patients are typically selected as candidates for therapy based upon clinical manifestation of the reaction in question. Thus, since the symptom is already present, it cannot be prevented. Prevention also encompasses the concept of 100% efficacy in 100% of patients, an endpoint which is often not reasonably attainable. Further, it is

known that bronchial hyperreactivity is caused and influenced by many different molecules and cells in a complicated manner, involving cytokines, leukotrienes, IgE, eosinophils, mast cells and the local epithelia itself (Buc et al., see entire document, particularly the paragraph spanning the left and right columns of page 341). Given the numerous agents involved in the development of bronchial hyperreactivity in asthma, it is not reasonable that any one single agent would globally stop 100% all of these various processes such that the breadth of the term "prevention" could reasonably be attained.

Therefore, based upon the breadth of the claimed invention, the guidance of the specification, and the teachings of the art, a skilled artisan would reasonably conclude that while bronchial hyperreactivity could be treated by administering anti-FcαI antibodies, such an administration would not reasonably prevent bronchial hyperreactivity.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 5, 6, and 8-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hudson et al. (WO 02/064634 A2, of record).

Hudson et al. disclose methods of administering antibodies which bind CD89/FcαRI to treat various diseases and disorders (see entire document, particularly the abstract). Such antibodies are disclosed as inhibiting and not inhibiting the binding of IgA to CD89 (see particularly pages 2-4). Given that the specification discloses that antibodies which bind the EC2 domain of CD89 do not inhibit IgA binding to CD89, the antibodies disclosed by Hudson et al. bind the EC2 domain. Monovalent fragments of

antibodies, such as Fab' fragments, are also disclosed (see particularly pages 3 and 11). The treatment of allergic asthma with anti-CD89 antibodies is also disclosed (see particularly pages 37-38). Preferred embodiments of such treatment methods use agents comprising an antibody which binds CD89 and another antibody which binds a heterologous antigen, such as IgE (ibid). It is further disclosed that such bispecific reagents are preferably made by combining monovalent fragments, such as Fab, Fab', Fv, and single chain constructs (see particularly lines 20-26 of page 40). As such, the reagents used in the methods of Hudson et al. comprise a monovalent Fab which binds CD89, thus meeting the structural requirements recited in the instant claims. Various routes of administration are disclosed, including injection and aerosol (see particularly pages 47-52). Given that the structure of the agent administered as part of the claimed methods is taught by Hudson et al., the intended effects of such an administration, such as inhibiting IgG phagocytosis and inhibiting IgE-mediated exocytosis, are inherent consequences of said administration. Applicant is reminded that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Therefore, the prior art anticipates the claimed invention.

7. Claims 5, 6, and 8-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Shen et al. (US 6,018,031, of record).

Shen et al. disclose methods of administering antibodies which bind CD89/FcαRI to treat various diseases and disorders (see entire document, particularly the abstract). Such antibodies are disclosed as inhibiting and not inhibiting the binding of IgA to CD89, and include the EC2-domain binding antibody A 77 (see particularly columns 2-4). Monovalent fragments of antibodies, such as Fab' fragments, are also disclosed (see particularly columns 8-10). The treatment of allergic asthma with anti-CD89 antibodies is also disclosed (see particularly columns 16-17). Preferred embodiments of such treatment methods use agents comprising an antibody which binds CD89 and another antibody which binds a heterologous antigen, such as IgE (ibid). It is further disclosed that such bispecific reagents are preferably made by combining monovalent fragments, such as Fab fragments (see particularly lines 20-29 of column 14). As such, the reagents used in the methods of Shen et al. comprise a monovalent Fab which binds CD89, thus meeting the structural requirements recited in the instant claims. Shen et al. also disclose treatment of asthma and allergies using Fab fragments of an anti-CD89 antibody conjugated to an allergen (see particularly columns 19-20). Such constructs would also be monovalent. Various routes of administration are disclosed, including injection and aerosol (see particularly columns 23-28). Given that the structure of the agent administered as part of the claimed methods is taught by Shen et al., the intended effects of such an administration, such as inhibiting IgG phagocytosis and inhibiting IgE-mediated exocytosis, are inherent consequences of said administration. Applicant is reminded that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are

necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Therefore, the prior art anticipates the claimed invention.

8. Claims 5, 6, and 8-19 are rejected under 35 U.S.C. 102(b) as being anticipated by van de Winkel et al. (WO 99/41285, of record).

van de Winkel et al. disclose methods of administering antibodies which bind CD89/FcαRI to treat macrophage-mediated diseases and disorders (see entire document, particularly the abstract). Such antibodies are disclosed as not inhibiting the binding of IgA to CD89, and include the EC2-domain binding antibody A 77 (see particularly page 13). Monovalent fragments of antibodies, such as Fab' fragments, are also disclosed (see particularly page 3). One disclosed method of treatment comprises the conjugation of a toxin to a Fab fragment specific for an Fc receptor such that upon administration macrophages expressing the receptor are bound by the immunotoxin and destroyed (see particularly pages 24-30). Note that such a construct is monovalent. Diseases disclosed as being treatable by administration of macrophage-binding compounds such as immunotoxins include allergic asthma (see page 48). As such, the reagents used in the methods of van de Winkel et al. comprise a monovalent Fab which binds CD89, thus meeting the structural requirements recited in the instant claims. Various routes of administration are disclosed, including injection and aerosol (see particularly pages 33-43). Given that the structure of the agent administered as part of the claimed methods is taught by van de Winkel et al., the intended effects of such an administration, such as inhibiting IgG phagocytosis and inhibiting IgE-mediated exocytosis, are inherent consequences of said administration. Applicant is reminded that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In

re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Therefore, the prior art anticipates the claimed invention.

Claim Objections

9. Independent claim 5 is objected to for the recitation of "monovalent antibody fragments directed against FcαRI receptor". While the meaning of the claim is reasonably obvious upon inspection of the specification, preferred claim terminology is "monovalent antigen-binding fragments of an antibody directed against FcαRI". Note that as presently written, the claim reads upon administering the Fc domain of IgA to patients (it is monovalent and binds FcαRI) even though such a concept does not appear to be supported by the text of the specification and explicit claiming of such a concept would likely be rejected as introducing new matter into the instant application. As such, the use of the proposed claim terminology is suggested.

10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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